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10/733,080	12/11/2003	Pascual Perez	A36102-PCT-USA-A	9528
21003 7590 07/10/2008 BAKER BOTTS L.L.P. 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112-4498				
EXAMINER				
KUMAR, VINOD				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
07/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DL.NYDOCKET@BAKERBOTTS.COM

Office Action Summary

Application No.

10/733,080

Applicant(s)

PEREZ ET AL.

Examiner

VINOD KUMAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 9 and 11-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 7, 9 and 11-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 09 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of Objections and Rejections

1. Applicant's response and amendment filed in the paper of April 14, 2008 is entered.
2. Claims 1-5, 7, 9 and 11-14 are pending.
3. Claims 6, 8, 10 and 15-21 are canceled.
4. Claims 1-5, 7, 9 and 11-14 are examined on merits in this Office action.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The objection to the specification has been withdrawn in light of amendment to the specification filed in the paper of April 14, 2008.
7. The objections to claims 1-3, 7, 11 and 12 have been withdrawn in light of claim amendment filed in the paper of April 14, 2008.
8. The rejection of claims 13 and 14 under 35 U.S.C. 112, 2nd paragraph has been withdrawn in light of claim amendment filed in the paper of April 14, 2008.

Election/Restriction

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

10. Claim 13 remains objected to because of the following informalities:

Claim 13 remains objected for not reciting --obtained from the F1 generation-- after "immature F1 embryos" in line 3.

Claim Rejections - 35 USC § 112

11. Claims 1-5, 7, 9, and 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "flanked by mobilizable sequence" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for the phrase "flanked by mobilizable sequence. This does not comply with written description requirements.

Dependent claims 2-5, 7, 9, 11-13 and 14 are also rejected because they fail to overcome the deficiency of parent claim 1.

This rejection has been necessitated due to the claim amendment filed in the paper of April 14, 2008.

Claim Rejections - 35 USC § 103

12. Claims 1-5, 7, 9, 11-13, and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (PCT, WIPO, Publication No. WO 98/38323 A, Published September 3, 1998, Applicant's IDS, an English equivalent published as US Patent Application No. US2002/0157129A1 on 24 October 2002) in view of Dellaporta et al. (Molecular cloning of the maize R-nj allele by transposon tagging with Ac, pp. 263-282, *in* Chromosome structure and function: Impact of new concepts, edited by J.P. Gustafson and R. Appels, Plenum Press, New York), Ishida et al. (Nature Biotechnology, 14(6):745-750, 1996), and Yoshida et al. (Journal of Bioscience and Bioengineering, 90:353-362, 2000) for the reasons of record stated in the Office action mailed on December 12, 2007. Applicant traverses the rejection in the paper filed on April 14, 2008.

Applicant argues that Perez et al. method results in the retention of a fixed transposase sequence as well as an antibiotic resistance gene in the final transgenic maize plants (response, pg 9, lines 3-6). Applicant further argues that although the selection and regulatory sequences are flanked by mobilizable sequences responsive to a transposase, Perez et al. note that the gene of interest is inserted outside of the mobilizable sequences and will thus be retained even if the sequence intervening the mobilizable sequence is excised (response, pg 9, lines 16-21). Applicant further argues that the final step of Perez et al. method leaves the gene of interest without any associated ancillary sequence from the first T-DNA vector. Applicant further argues that the transposase introduced by the second T-DNA vector is fixed and is incapable of excising

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itself. Applicant further argues that Perez et al. method involves the retention of a significant amount of ancillary sequence, including the problematic antibiotic resistance gene (response pg 10, lines 19-25).

Applicant's arguments are fully considered but are deemed to be unpersuasive.

It is maintained that Perez et. al. teach a method for obtaining a transgenic maize plant containing coding sequence of interest (male sterility, AMS) that is free of foreign ancillary sequence, wherein the method comprises the following steps: (a) transforming at least one active transposase-free maize plant cell with a transformation vector comprising two expression cassettes, one of which contains a nucleotide sequence of interest (male sterility, AMS) another a nucleotide sequence coding for a selection marker (nptII, antibiotic resistance or bar, herbicide resistance) flanked by the mobilizable sequences of a transposon (Ac/Ds), wherein said expression cassette containing a nucleotide sequence of interest (i) is outside said transposon element; (b) selecting the transformed plants using said selection marker; (c) cross-breeding a transformed plant with another plant from a line containing, in the genome thereof, a gene coding for an endogenous active transposase (Ac) and located within a phenotypic excision marker sequence encoding GUS, in order to produce an F1 individual or any subsequent progenies; (d) selecting, from the F1 generation, cells or individuals carrying the gene of interest and free of foreign ancillary sequences; (e) regenerating plants using the cells or individuals selected in step (d). See in particular, claims 4-12; examples 1-12; figures 1-3, pages 1-16.

Applicant's attention is also drawn to claims 4 and 9-11 of Perez et al., wherein the reference clearly teaches elimination of undesirable DNA fragment including antibiotic resistance marker gene from their transgenic plants.

It is further maintained that at the time the invention was made, it would have been prima facie obvious and within the scope of an ordinary skill in the art to modify the method of making a transgenic maize plant containing a coding sequence of interest that is free of ancillary selection marker as taught by Perez et al., to substitute the second parental maize plant of Perez et al. with a maize plant as taught by Dellaporta et al. which has within its genome a sequence encoding an endogenous active Ac element transposase.

It is further maintained that it would have been obvious and within the scope of an ordinary skill in the art to expect that Dellaporta et al. transposase would have operated on the mobilizable sequence of Perez et al. second expression cassette with a reasonable expectation of success. It is further maintained that the F1 selected plants from said modified method would have the endogenous active Ac element transposase excised, thereby producing anthocyanin-containing sectors on the crown of the seed, to identify maize plant or cell containing Perez et al. coding sequence of interest, but lacking Perez et al. ancillary selection marker coding sequence with a reasonable expectation of success.

It is further maintained that one of ordinary skill in the art would have been motivated to do so for the purpose of replacing a non-natural phenotypic marker (GUS) for excision as taught by Perez et al. with a naturally occurring phenotypic

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marker (anthocyanin) for excision as taught by Dellaporta et al. to obtain a transgenic plant comprising the coding sequence of interest, which is free from foreign ancillary marker, and foreign phenotypic marker for excision with a reasonable expectation of success.

It is further maintained that it would have been prima facie obvious to one skilled in the art at the time the claimed invention was made to modify Perez et. al. method of obtaining a transgenic corn plant containing a coding sequence of interest that is free from foreign ancillary sequence, by using corn inbred line A188 as taught by Ishida et al. The motivation to do so comes from Ishida et al. who teach that transformation of embryogenic callus A188 resulted in higher frequency of fertile transgenic corn plants, compared to embryogenic callus derived from other inbred lines.

It is further maintained that it would have been obvious and within the scope of an ordinary skill in the art to use any selective marker in the second expression cassette of Perez et al. including a coding sequence encoding a nondestructively detectable green fluorescent protein as taught by Yoshida. One of the ordinary skill in the art would have been motivated to do so for the purpose of obtaining primary transformants that could have been visually selected without destroying the transgenic plant.

It is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the

combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, one of ordinary skill in the art would have arrived at the instantly claimed invention by combining the prior art teachings of Perez et al., Dellaporta et al. Ishida et al. and Yoshida et al. with a reasonable expectation of success.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, one of ordinary skill in the art would have arrived at the claimed invention by combining the prior art teachings of Perez et al., Dellaporta et al. Ishida et al. and Yoshida et al. with a reasonable expectation of success.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

13. Claims 1-5, 7, 9, 11-13, and 14 remain rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VINOD KUMAR whose telephone number is (571)272-4445. The examiner can normally be reached on 8:30 a.m. to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phuong T. Bui/
Primary Examiner, Art Unit 1638